final surface. The Examiner takes the position that the specification fails to provide some standard by which the roughness of the surface or the degree of removal of the oxide surface could be determined when the term "substantially" is used. Reconsideration is requested.

While the term "substantially" may be considered a broad term, here should be understood as leaving open the possibility of some variation which has no significant effect on the property being described.

Consider the meaning of "substantially uniform surface texture," a phrase which is literally found at column 5, line 29, of the parent U.S. 5,876,453. It should be evident from viewing the photographs that words cannot fully describe the topography of the surface and that the magnification of the photographs presents different perspectives. Residual native oxide will limit the ability of the etching acids to create the desired uniformly rough surface. FIG. 3 of parent U.S. Patent No. 5,876,453 is a sketch illustrating the point. If native oxide (14) remains, then the acids are unable to etch the metal uniformly, since they are unable to remove the native oxide completely. Example 2 illustrates such "non-uniformly etched "surfaces in Fig. 3. The Examiner's assertion that Fig. 3 falls within the meaning of substantially uniform irregularities is not supported by Example 2.

With regard to use of the word "substantially" in connection with removal of the native oxide, this is literally used at column 5, lines 25-29, of the '453 patent ". . . *it is important to remove substantially all of the native oxide from the implant surface . . . so that subsequent treatment of that surface produces a substantially uniform surface texture . . .*" The method for determining the depth of the native oxide is by AES, as discussed at column 4, lines 1-30, of the '453 patent, and illustrated in FIG. 5 (FIG. 7 of U.S. Patent No. 5,876,453). That conventional technique for measuring the depth of oxides on the surface of metals can assure one skilled in the

art that the native oxide has been removed. In the discussion at column 5 of the '453 patent, it is reported that the preferred 15% HF solution can etch the oxide at about 200-350 Angstroms/minute and that in about one-half minute all the native oxide will have been removed, since the native oxide thickness is normally about 70-150 Angstroms. *"The preferred 15% HF solution allows substantially complete removal of the native oxide layer with minimum further consumption of the titanium surface . . ."* (see column 5, lines 18-21, of '453). It should be clear that practicing the techniques taught in the specification will provide a surface which can be considered "substantially" free of native oxide.

Further, the Federal Circuit has consistently ruled that terms like "substantially" or "about" present an acceptable way for the patentee to ensure that he or she will not have to rely solely on the doctrine of equivalents to prove infringement when competitors try to avoid the patent by insignificant changes. See Ahmil Enterprises v. Wawa, Inc., 81 F.3d 1554 (Fed. Cir. 1996); Pannu v. Iolab Corp., 155 F.3d 1344 (Fed. Cir. 1998).

Therefore, the Applicants submit that the rejection of claims 11-21, 27-33, 35-49 and 51-56 under 35 U.S.C. § 112 should be withdrawn in view of the teachings of the specification.

II. Rejections Based On Krueger

Claims 11-16, 22-25, 27-33, 35-49 and 54-56, were rejected under 35 U.S.C. § 102(b) as anticipated by Krueger or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Krueger alone. The Examiner asserts that at least one of the intermediate or final product of Kreuger would have the native oxide layer removed and would have irregularities of less than 10 microns.

The text of the Krueger patent is too vague, however, to support such a conclusion. Krueger says only that the etching techniques correspond to those used in etching the electrodes of electrolytic capacitors and are not set forth in detail. This disclosure could not enable one

skilled in the art to understand or duplicate the methods used by Krueger. Therefore, the Applicants contend that the Krueger reference does not anticipate, since reference cannot anticipate when it does not enable, MPEP 2121. The Examiner has suggested that the Applicants duplicate Kreuger to etch with mineral acid to an etch ratio greater than two. In response, a series of tests has been carried out, which will be reported shortly in a declaration under 37 C.F.R. 1.132. The Examiner is asked to carefully review these results.

Claims 51-53 were rejected under 35 U.S.C. § 103(a) as unpatentable (obvious) over Krueger in view of Wagner et al. (Wagner). As the Examiner recognized, Krueger did not teach including both roughened and unroughened sections in his implant. Wagner does teach the use of differing degrees of roughness in his implants. He does not, however, teach the use of a smooth section which extends about 3 mm down from the top of the implant, typically including the uppermost threads. Instead, Wagner teaches the use of three different types of surfaces, none of which are acid etched. Only one is said to be grit-blasted to roughen the surface in a narrow band near the top. Thus, if one skilled in the art were to look to Wagner, he would have to adapt those teachings radically to use them in the threaded implant of Krueger. There would be three different surface textures, none of them acid etched. Wagner does not recognize the benefits of providing a roughened surface on threads since, in the alternative embodiment of FIG. 4, the threads apparently are not roughened at all, while the upper portion of the implant remains the same as FIGS. 1 and 3.

It appears that Wagner should not be considered to be prior art to the present application, which claims the benefit of earlier applications including PCT/US95/6595 of November 30, 1995. Wagner has a 102(e) date of October 2, 1997, and a PCT publication date of June 19, 1997 and should be withdrawn as a reference.

III. Rejections Based On Schulte

Claims 11-16, 22, 24, 25, 27-33, 36-49 and 54-56 were rejected under 35 U.S.C. § 102(b) as anticipated by the Schulte et al. 1992 article (Schulte) or as obvious under 35 U.S.C. § 103(a).

The Examiner notes that the irregularities are 2-5 microns high and substantially uniform, especially pointing to FIG. 14. The Applicants cannot agree that the only question is whether the Schulte implant is identical or substantially identical. The Schulte article contains very little information regarding titanium implants, since the main emphasis of the investigations was with aluminum oxide implants. On page 8, the authors begin to discuss the Frialit®-2 system. With regard to the surface of the titanium, they say, *"[t]he titanium surface is sandblasted and etched to achieve a relative increase in area compared to the bone . . ."* FIG. 13 shows the surface of a Frialit-2 stepped screw after blasting with aluminum oxide powder. FIG. 14 shows the surface of the stepped screw after "acid etching." It is not clear whether the surface of FIG. 14 is the result of the aluminum oxide blasting of FIG. 13 followed by acid etching. Even if it is assumed to be the case, the Schulte article is silent on the type of acid etching that was used. One skilled in the art would learn little from such as disclosure. As with Krueger, information needed to duplicate the Frialit-2 implant has been omitted. The Schulte 1992 article does not disclose enough information to make it an anticipation of the presently claimed implants, or to make the present claims obvious. In the Third Information Disclosure Statement mailed August 6, 2001, it is explained that Friatec, like Steri-Oss, appears to have chosen to keep the details of its process for roughening their implant surface a trade secret.

IV. The Porter Declaration

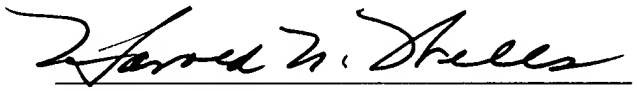
The Applicants object to the Examiner's position with regard to a good faith effort to demonstrate commercial success. It appears that the Examiner expects more information is needed, some derived from third parties, but not available to the Applicants. Further, the Examiner seems to presume that marketing determined success, rather than the merits of the product, an assumption difficult, if not impossible to rebut.

The Applicants include herewith a Seventh Information Disclosure Statement for the Examiner's consideration.

It is the Applicants' belief that all of the claims are in condition for allowance. If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is invited to contact the undersigned attorney at the number indicated.

Respectfully submitted,

Date: January 16, 2003



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